Medical Device Regulatory Requirements for Kenya

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Introduction to the Kenyan Medical Devices Regulatory System

Ministry of Health (MOH) in Kenya is the government agency charged with meeting Kenyan's health care needs and regulations. The Kenyan medical market relies almost entirely on the imports of medical equipment. Locally produced medical devices account for less than 1% of the market, with the rest being imported. Kenya's health system consists of both public and private sectors.

Medical Regulations

Most medical products have ready access to Kenya as long as they meet Kenya Bureau of Standards (KEBS) requirements. Although generally easy to obtain, they can be Kenya-specific and/or subject to a certain degree of arbitrary interpretation. KEBS requirements are being enforced more rigorously than in the past through Pre-shipment Verification of Conformity to standards program (PVoC).

On September 29, 2005, KEBS began implementation of the PVoC, a conformity assessment and verification procedure applied to specific "Import Regulated Products" from exporting countries to ensure compliance with the applicable Kenyan technical regulations and mandatory standards or approved equivalents (international standards and national standards). The Government of Kenya (GOK), through KEBS, now requires that all consignments of regulated products entering Kenya must obtain a Certificate of Conformity issued by one of two firms: Société Générale de Surveillance S.A. (SGS), or Intertek. Exporting countries must now certify that goods comply with Kenya Bureau of Standards requirements prior to shipment. The issued certificate is a mandatory customs clearance document in Kenya; consignments of regulated products arriving at Kenyan Customs Points of Entry without this document will be subject to delays and possibly denial of admission into Kenya. However, medical devices classified under Harmonized Tariff System chapter 90 are not subject to PVoC regulations but are instead subject to a destination inspection by KEBS.

U.S. suppliers of electro-medical equipment need to consider voltage specifications for Kenya. Adaptation requires conformance to Kenya's 240V electric power supply system or at least provide a switch option between the U.S. 120V system and the latter.

The Kenyan Ministry of Health requires that suppliers of diagnostic kits and reagents that test for sexually transmitted infections (including HIV/AIDS and hepatitis) carry out evaluations to ascertain the reliability of these products. Medical device product evaluations can be done by the National Public Health Laboratories and typically involve 400 tests at a cost of about $1000.

Licensing

The import climate for U. S. medical equipment market in Kenya is attractive. The following documentation is required to facilitate importation of medical equipment:

- Import declaration form (IDF)
- Commercial invoice
- Airway bill ((airfreight) or bill of lading (sea freight) and
- Certificate of Analysis from the foreign supplier/manufacturer of the equipment to facilitate destination inspection by the Kenya Bureau of Standards

The cost of an IDF is 2.75% of the accumulative cost, insurance and freight (C.I.F) value, payable as an import declaration-form (IDF) processing fee. If not indicated, freight is calculated at 18.5% of the consignment cost, and insurance 1.5% of the sum of the consignment cost and freight.

Following the January 2005 introduction of an East African Community Common External Tariff, all categories of medical equipment are exempt from both import duties and value added tax (VAT), including microscopes, dental chairs and liquid-filled clinical thermometers, which were hitherto subject to import duties and VAT. No approval is required to import any kind of irradiation device. However, prior to installation of any irradiation device the Radiation Protection Board must conduct an inspection and thereafter grant a license.

There is no ban on the import of any type of pre-owned (used and refurbished) medical equipment to Kenya as long as the performance characteristics conform to the existing national standards and since none exist, reference is made to the International Standards Organization.

Trademark

The trademark name and country of origin must be displayed in English and/or

Kiswahili for all categories of medical equipment. In addition, an expiry date must be shown for all medical consumables.

Distributor/Agents

Kenya has no requirement for the retention of a local agent or distributor by a U.S. or other foreign company exporting to Kenya**.** Success in the Kenya's medical devices market typically requires that U.S. suppliers establish a permanent presence within the country, either directly owned or through an agent or local representative. A local representative can provide the U.S. supplier with vital market information, personal networks, and technical assistance – especially when bidding on GOK procurements for laboratory equipment, scientific instruments and diagnostics**.**

Although the Kenyan market for medical devices present no unique or particular marketing problems for U.S. suppliers, the long distance from U.S. manufacturers usually requires that the local dealer or distributor stock higher than normal levels to compensate for longer freight times. Price and compatible technical specifications are usually the major considerations when deciding to purchase goods. Other than setting up a manufacturing plant, U.S. manufacturers and exporters are best served by establishing a local representative as the most realistic market penetration strategy for Kenya.

Kenya traditionally does not have an effective backup-service and after-sales support. If the product to be exported requires servicing, qualified service personnel and a reasonable supply of spare parts must be considered. Failure to address the issue of after-sales support and service is a major impediment to success in this market. To locate a local agent, distributor, or a partner, U.S. business representatives should contact the nearest U.S. Department of Commerce Export Assistance Center (USEAC) and request an International Partner Search (IPS) or a Gold Key Service (GKS). Nominal fees are charged for these services.

Procurements are mainly achieved through Government tender or direct purchase. Consequently, the local representative/dealer ought to have good contacts in Kenya and access to the appropriate decision making authorities. U.S. suppliers should contact hospitals directly. Purchasing decisions are based primarily on reasonable prices, acceptable quality, product reputation, and availability of after sales service, repair, and maintenance.

Payments/Financing

There are several basic methods of receiving payment for medical device products in Kenya, the selection of which is usually determined by the degree of trust in the buyer's ability to pay. Payment alternatives that U.S. exporters might consider, in order of the least to most secure include: consignment sales;

open account; documentary drafts for collection; irrevocable letter of credit; confirmed irrevocable letter of credit; and cash in advance.

All major Kenyan commercial banks have correspondent banks in the United States of America. Landed product prices are arrived at by applying the determination of cost formula. In the case of imported goods, the following is the sum total:

- FOB costs, as per bill of lading;
- Net sea/airfreight charges
- Insurance;
- Shipping agents fee;
- Port charges;
- Clearing and forwarding charges (generally up to 0.5% of FOB cost); and
- Land transport costs.

U.S. manufacturers and exporters can obtain financing for their exports from the Export-Import Bank (EXIM) of the United States of America. This bank is the official U.S. agency involved in providing credits to help finance U.S. exports. While EXIM engages in direct lending, both to foreign buyers and to intermediate private parties who lend to buyers, the bulk of its export- financing assistance is in the form of loan guarantees and export credit assurance.

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